DEC - 2 2011

Shanghai Dynamic Industry Co., Ltd.
No. 6 building, No. 4588 Jiasong (M) Rd., Qingpu District, Shanghai, China

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K111907
Date:	June 20th, 2011
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Shanghai Dynamic Industry Co., Ltd. No. 6 building, No. 4588 Jiasong (M) Rd., Qingpu District, Shanghai, China
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] E-mail: doris_d@126.com Tel: 86 21-31261348 Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	DYNAMIC® DU Series Portable Dental Unit
Common Name:	Dental Operative Unit
Classification Name:	Dental operative unit and accessories
Regulation Number:	872.6640
Product Code:	EIA
Device Class:	I
Submission Type:	510(k)
Review Panel:	Dental
Indications for use:	The DU Series Portable Dental Unit is intended to supply power and serve as a base for dental devices and accessories. This device delivers air, water, vacuum, and electricity to handheld instruments, for use in dental clinics and hospitals. It is designed to be used by professional dental practitioners.
Device Description:	1) The DU Series Portable Dental Unit is a combination of the speed handpieces, ultrasonic scaler, curing light, 3-way syringe, saliva ejector, clean water bottle, drain bottle, oil free air compressor, and footswitch. 2) The external AC power source provides electric power to the unit. The self contained air compressor provides air source to speed handpieces. The self contained water system provides water source for the syringe, handpieces and ultrasonic scaler. 3) The speed handpiece is supplied by the manufacturer of Predicate Device K991701; the ultrasonic scaler is supplied by K053555; the curing light is supplied by K080025. Other accessories are self-produced. 4) The patient contacting components are in the accessories of speed handpieces and the ultrasonic scaler. All the patient-contacting materials have passed biocompatibility testing according to ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
Performance data:	Bench testing has been performed on a sample against the standards of ISO

7494-2:2003 and ISO 9168:2009, and found it in compliance with the standards.

3. Substantial Equivalence:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

Predicate 510(k) Number:	K022217
Marketing clearance date:	Oct 24, 2002
Product name:	AEU-425 Transport II Portable Electronic Dental Operative System
Manufacturer:	ASEPTICO, INC.
Equivalence conclusion:	In all important respects, the DYNAMIC@ DU Series Portable Dental Unit are substantially equivalent to the AEU-425 Transport II Portable Dental System (K022217). This conclusion is based upon comparison on design, technical characteristics, operation mode, intended use, and safety standards complied with. Any differences in the technological characteristics do not raise any new safety and effectiveness issues.

4. Safety and Effectiveness of the device:

The DU Series Portable Dental Unit has passed bench testing according to
ISO 7494-2:2003 Dentistry - Dental units - Part 2: Water and air supply
ISO 9168:2009 Dentistry - Hose connectors for air driven dental handpieces
and safety testing according to
EN 60601-1:2006 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

The handpieces and ultrasonic scaler, which are supplied by 510(k) approved manufacturers, have passed the biocompatibility testing according to ISO 7405 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.

The conclusion drawn from the bench testing and safety testing is that the device is as safe and effective as the predicate device. Furthermore, the device complies with the recognized standards and performs its intended tasks as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shanghai Dynamic Industry Company, Limited
C/O Ms. Doris Dong
Manager
Shanghai CV Technology Company, Limited
RM 1706, No. 128 Songle Road
Songjiang Area
Shanghai
CHINA 201600

DEC - 2 2011

Re: K111907
Trade/Device Name: DYNAMIC® DU Series Portable Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: November 17, 2011
Received: November 23, 2011

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K111907

Device Name: DYNAMIC® DU Series Portable Dental Unit

Indications for Use: The DU Series Portable Dental Unit is intended to supply power and serve as a base for dental devices and accessories. This device delivers air, water, vacuum, and electricity to handheld instruments, for use in dental clinics and hospitals.
It is designed to be used by professional dental practitioners.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Susan Runyon

Division Sign-Off
Division of Surgical, Orthopedic,
And Restorative Devices

510(k) Number K111907

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111907